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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,563	10/05/1999	LEO K. VAN ROMUNDE	SCQ-001USRCE	6102
959 7590 02/11/2008 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER WU, RUTAO	
			ART UNIT 3628	PAPER NUMBER
			MAIL DATE 02/11/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/402,563

**Applicant(s)**

VAN ROMUNDE ET AL.

**Examiner**

ROB WU

**Art Unit**

3628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-10,12-14,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-14,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. In response filed August 13 2007, the Applicant amended claim 1 and 12. No claim has been canceled or introduced by this amendment. Accordingly claims 1-3, 5-10, 12-14, 16 and 17 are pending in the application.

### ***Response to Arguments***

2. Applicant's arguments, see page 5, filed August 13 2007, with respect to claims 1 and 12 have been fully considered and are persuasive. The 35 U.S.C. §112 rejection of claims 1 and 12 has been withdrawn.
3. Applicant's arguments filed August 13 2007 have been fully considered but they are not persuasive.

Regarding claim 1, the Applicants allege that McIlroy (U.S. Pat No. 5,583,758) does not teach or disclose the limitations of claim 1, specifically McIlroy does not teach a hierarchised sequences of alternative actions, that is, ranked sequence of actions. The Examiner respectfully disagrees. McIlroy discloses his system that "[leads] to an endpoint that is usually one guideline treatment option. However, the endpoint may also be two or more alternative treatments." (col 5: lines 16-19) From this disclosure it can be seen that the treatment options are ranked at least in the order of effectiveness or importance in treating a particular patient, otherwise the system is not able to recommend treatment options.

The Applicant also states that Mcllroy give no indication that the guideline treatment constitutes "all other treatments not chosen by the user" as set forth in claims 1 and 12. The Examiner does not agree with the Applicant's assertion, there is no reason for Mcllroy not to present all available treatments under Recommended Treatment as shown Fig 24A as long as the treatment is related to the diagnosed condition. Even if the Applicant's assertion were true, it would have been obvious for Mcllroy to evaluate the actions based on the past history of all alternative actions including both the treatment chosen and all other treatment not chosen by the user. Mcllroy would be motivated to do so to be able to arrive at the most relevant recommend action, since in the case of medical diagnosis, misdiagnoses or mistreatment could be a matter of life or death situation.

The Applicant also asserts that Mcllroy does not teach or disclose claims 1 and 12 in that in Mcllroy any recording of the sequence takes place after the selection and normally is not used thereafter to steer the process. The Examiner respectfully disagrees. Mcllroy discloses his system to permit continuous updating and modification of the experience base, using the information input into the process for each case. For example, the information on actual treatment provided can be used to reassess the decision path for system-selected treatments. (col 2: lines 25-30) Furthermore, Fig 24A of Mcllroy's invention allows for reconstruction of the whole decision making sequence including the sections thereof comprising alternatives that were not chosen in the end.

In light of the foregoing responses, Claims 1 and 12 stand rejected over Mcllroy.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5-10, 12-14, 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat No. 5,583,758 to McIlroy et al.

As per claims 1, 12,

A method for electronically storing, retrieving and modifying records using a computer system comprising a display unit, an input unit, a memory unit and a processing unit; McIlroy teaches this limitation at column 4 lines 50-56)

Involving at least one recorded catalogue of recommended actions; McIlroy teaches this limitation by disclosing "a treatment component that presents the guideline treatment options, and highlights the guideline-selected option(s) based on user responses to questions." (col 6: lines 4-6) and "The treatment component also uses data bases. FIG 7 is an example of a guideline treatment data base set for the condition corresponding to guideline. In general, for each guideline identified by a five digit number in field 25, there are listed one or more treatment options. " (col 7: lines 13-17) The treatment component as disclosed by McIlroy include lists of treatment options, and therefore teach at least one recorded catalogue of recommended actions.

And for sequentially steering a process of interrelated actions from said at least one recorded catalogue of recommended actions; McIlroy teaches the limitation by

disclosing "the system presents each guideline in a questioning logic sequence where the response to each question drives to the next question or to the appropriate treatment options. (col 5: lines 33-35)

Wherein said at least one recorded catalogue of recommended actions comprises hierarchised [*sic*] sequences of alternative actions. Mcllory teaches said limitation. In FIG 15 of Mcllory's invention, it can be seen that a list of recommended actions are shown (2A, 2B, 2C, 4A), within the list of recommended actions, actions 2C and 4A are alternative actions since 2A and 2B are chosen as the recommended treatments. It is also clear that Mcllory's actions are an ordered sequence of actions because the actions are labeled as 2A, 2B, 2C and 4A.

Wherein said recommended and alternative actions comprise sequential procedure steps and wherein for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms. Mcllory teaches the limitation. From FIG 16 of Mcllory's invention it can see that the actions comprise sequential procedure steps. For example, action 2B calls for sequential procedure steps of "Streptokinase or urokinase for 3 days followed by 6 days heparin with coumadin initiated by day 2 of heparinization." Mcllory teaches for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms by disclosing that reports that

show diagnostic decision outcome profiles and procedure decision outcome profiles are generated. (col 16: lines 57-59; Fig 24A)

Wherein said evaluation forms comprise a list of one or more selected from the group comprising of recommended actions, information-input requests, decision-requests and selection algorithms. Mcllory teaches the limitation by showing that in FIG 24A the form that shows recommended actions, information-input requests and decision-requests (Proposed Treatment and Recommended Treatment)

And wherein said generation of evaluation form is carried out in function of said hierarchised [*sic*] sequences of alternative actions, and in function of the past history of all alternative actions, including both the actual treatment chosen and all other treatment not chosen by the user. Mcllory disclose in FIG 24A a specialist review work sheet that shows a recording of the sequences made before, during, and after the selection process, allowing for reconstruction of the whole decision making sequence including the sections thereof comprising alternatives that were not chosen in the end. In FIG 24A the actions that let up to the treatments are recorded and shown (239 and 240), the recommended treatment is recorded and shown (237) and the alternative treatments that are not chosen by the user are also recorded and shown (238)

so as to enable transfer of a group of evaluation forms and subforms in one operation into one file. Since Mcllory disclose the specialist review work

Art Unit: 3628

sheet it is obvious to one skilled in the art that the evaluation forms and subforms are transferred in one operation into one file.

As per claims 2, 13, McIlroy, et al discloses:

Wherein said at least one recorded catalogue of recommended actions comprise associated electronic selection algorithms in respect of the hierarchised sequences of alternative actions...(col. 3, line 2-4).

As per claim 3, 14, McIlroy, et al discloses:

Wherein said selection algorithms are integrated in said generated electronic forms...(Figs 10-17).

As per claim 5, 16, McIlroy, et al discloses:

Wherein said evaluation form comprises information from records relevant for a decision-request...(col. 5, lines 56-65).

As per claim 6, 17, McIlroy, et al discloses:

Wherein a record of information entered and used is stored in said memory unit... (col. 4, lines 56-59).

As per claim 7, McIlroy, et al discloses:

Wherein a record of the information and actions entered and used is stored in the memory unit of the purpose of measurement of the effectivity and/or efficiency of effects and/or results of the procedure...(col. 18, lines 16-20).

As per claim 8, McIlroy, et al discloses:

Wherein the method involves a supervising organization for the purpose of quality control and quality improvement...(col. 18, lines 20-22).



As per claim 9, McIlroy, et al discloses:

Wherein the method allows for updating of the recorded catalogue(s) of recommended actions... (col. 10, lines 14-15).

As per claim 10, McIlroy, et al discloses:

Wherein said supervising organization evaluates the effectivity and/or efficiency of effects and/or results based on said records of information and actions used/entered, stored during use of the method, and updates the recorded catalogue(s) of recommended actions in function of said evaluation...(col. 3, lines 21-25).

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rob Wu whose telephone number is (571)272-3136. The examiner can normally be reached on Mon-Fri 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Hayes can be reached on (571)272-6708. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. W./

Examiner, Art Unit 3628

/JOHN W HAYES/

Supervisory Patent Examiner, Art Unit 3628